PRESCRIBING INFORMATION
PRODUCT MONOGRAPH

HUMATIN*CAP
(Paromomycin Sulfate Capsules MANUFACTURER STANDARD)
250 mg Capsules

ANTIBIOTIC

8250 Décarie Blvd, suite 110
Montréal, QC
Canada, H4P 2P5

DATE OF PREPARATION
January 08, 2001

DATE OF REVISION
February 19, 2013

Control No. HUMPM01
HUMATIN (Paromomycin Sulfate Capsules MANUFACTURER STANDARD)

250 mg Capsules

THERAPEUTIC CLASSIFICATION
Antibiotic

ACTION AND CLINICAL PHARMACOLOGY

HUMATIN (Paromomycin Sulfate) is a broad spectrum aminoglycoside antibiotic produced by Streptomyces rimosus var. paromomycinus. The drug is structurally related to neomycin, streptomycin and kanamycin.

It is poorly absorbed after oral administration with almost 100% of the drug recoverable in the stool.

Paromomycin sulfate is considered a luminal or contact amebicide since it acts principally in the intestinal lumen.

Unlike tetracyclines, paromomycin is a direct-acting amebicide and is effective either in the presence or absence of bacteria.

Like other aminoglycosides, paromomycin is bactericidal and appears to inhibit protein synthesis in susceptible bacteria at the 30S segment of the ribosome.

Paromomycin sulfate has a broad spectrum of activity, including activity against protozoa, bacteria and cestodes.

Paromomycin sulfate is active against protozoa, especially E. histolytica. The drug is believed to act against both the trophozoite and encysted forms of Entamoeba.

Paromomycin sulfate has an antibacterial spectrum quite similar to that of neomycin and is bactericidal to many normal and pathogenic organisms in the gastrointestinal tract. Almost complete cross-resistance exists between paromomycin and kanamycin, neomycin and streptomycin.
INDICATIONS AND USAGE

HUMATIN (Paromomycin Sulfate) is indicated for the treatment of intestinal amebiasis, acute and chronic.

(NOTE—It is not effective in extraintestinal amebiasis).

CONTRAINDICATIONS

Individuals with a history of previous hypersensitivity reactions to HUMATIN (Paromomycin Sulfate). It is also contraindicated in intestinal obstruction.

PRECAUTIONS

The use of HUMATIN (Paromomycin Sulfate), as with other antibiotics, may result in an overgrowth of nonsusceptible organisms, including fungi. Constant observation of the patient is essential. If new infections caused by nonsusceptible organisms appear during therapy, appropriate measures should be taken.

The drug should be used with caution in individuals with ulcerative lesions of the bowel to avoid renal toxicity through inadvertent absorption.

ADVERSE REACTIONS

Nausea, abdominal cramps and diarrhea have been reported in patients using HUMATIN (Paromomycin Sulfate), on doses over 3 g daily.

DOSAGE AND ADMINISTRATION

Adults and Children: Usual dose of HUMATIN (Paromomycin Sulfate) is 25 to 35 mg/kg body weight daily, administered in 3 doses with meals, for 5 to 10 days.

Capsule Composition

Each HUMATIN (Paromomycin Sulfate) capsule contains: paromomycin sulfate equivalent to paromomycin 250 mg. Non-medicinal ingredients: Each capsule contains: colloidal silica, magnesium stearate. Capsule shell: yellow iron oxide, black iron oxide, red iron oxide, gelatin and titanium dioxide.
Stability and Storage Recommendations

Store HUMATIN (Paromomycin Sulfate) at controlled room temperature 15 - 30°C. Protect from moisture.

AVAILABILITY OF DOSAGE FORMS

HUMATIN (Paromomycin Sulfate) capsules are available in the dosage strength of 250 mg per capsule.

Each capsule has a coni-snap No1 brown cap and a yellow body with no print.

Available in bottles of 100.

PHARMACEUTICAL INFORMATION

Drug Substance

Proper Name: Paromomycin Sulfate

Chemical Name: \(O-2\text{-amino-2\text{-deoxy-}\alpha\text{-D-glucopyranosyl-(1→4)-O-[O-2,6\text{-diamino-2,6\text{-dideoxy-}\beta\text{-L-idopyranosyl-(1→3)-}\beta\text{-D-ribofuranosyl-(1→5)]-2\text{-deoxy-}\beta\text{-D-streptamine sulfate(salt).}}}}\)

Empirical Formula: \(C_{23}H_{45}N_5O_{14} \cdot xH_2SO_4\)

Molecular Weight: 615.64 (Base)

Structural Formula:

\[\text{[Diagram of structural formula here]}\]
Description: It is a white, amorphous, stable water-soluble product. Paromomycin Sulfate is the sulfate salt of an antibiotic substance or substances produced by the growth of *Streptomyces rimosus var. paromomycinus*, or a mixture of two or more such salts. It has a potency equivalent to not less than 675 μg of paromomycin (C_{23}H_{45}N_{5}O_{14}) per mg, calculated on the dried basis.